

DP BARCODE No.: D355153 File Symbol No.: 264-RNTE(a) PRODUCT NAME: Proceed MD Fungicide

DATE OUT: 05 / AUG / 2008

SUBJECT: FEE.PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D355153 File Symbol No.: 264-RNTE (a)
PRODUCT NAME: Proceed MD Fungicide
COMPANY: Bayer Cropscience LP
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 113501, 113961, 128997; Decision No. 386008; Action Code: R170

FROM: Shyam B. Mathur
Product Chemistry Team Leader
Technical Review Branch / RD (7505P)

S B Mathur
8/5/08
TM

TO: Bryant Crowe / Tony Kish, RM 22
Fungicide Branch / RD (7505P)

INTRODUCTION:

The product chemistry data, the CSF for basic formulation (B010, dated 01-03-08) and two CSF's for alternate formulations (A010 & A020, both dated 01-03-08) along with the product label were reviewed previously by TRB (see PCR dated 06-26-08; DP352187 & 347125). The product chemistry data and all the submitted CSF's were found to be acceptable. The applicant has now submitted an additional alternate CSF (Alt # 3, A030) dated 06-17-08 for the proposed end use product. TRB has been asked to determine the acceptability of the proposed alternate CSF #3.

SUMMARY OF FINDINGS

1. The proposed end use product contains Prothioconazole Technical [Reg. No. 264-824, 97.74%], Tebuconazole technical [Reg. No. 264-748, 95.37%], and Metalaxyl [redacted] as the active ingredients with product label claims of 1.47%, 0.29% and 0.59% respectively.
2. The CSF for alternate formulation #3 (A030) dated 06-17-08 is filled out correctly & completely. The nominal concentrations of the active ingredients concur with the product label claim nominal concentrations. The CSF for alternate formulation #3 (A030) is in compliance with PR Notice 91-2 and 40 CFR§152.43. All the food use inert ingredients present in the formulation are approved by the Agency (IIAB, 06-27-08) and have tolerance exemption for growing crops only. The certified limits for the AI and inert ingredients are in compliance with standard certified limit table set forth in 40CFR§158.350(b)(2), except for three food use inert ingredients. The registrant has proposed wider certified limits for three of the food use inert ingredients which are present as the [redacted] in the formulated product. No justifications have been provided for the proposed certified limits. The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the product chemistry data requirements of 40CFR§158.320 & 158.350 respectively.
3. The pH value for the alternate CSF #3 (dated 6-17-08) is 6.9-8.2 which is indicative of its slightly basic nature as compared to basic formulation (dated 6-13-08) which showed pH value of 5-7 (acid-neutral).

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

CONCLUSIONS:

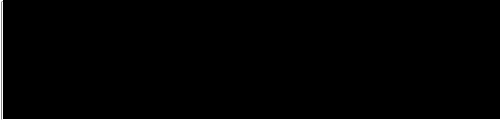
The TRB has reviewed the proposed CSF for alternate formulation #3 (dated 6-17-08, A030) and has concluded that:

1. The proposed CSF for alternate formulation #3 (A030 dated 06-17-08) is acceptable with condition. The registrant is advised to provide the justifications for proposing wider certified limits for three of the food use inert ingredients. For the names of these inert ingredients, please refer to Confidential Appendix.
2. As has been indicated previously, the registrant must submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies on completion.

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CONFIDENTIAL APPENDIX

Names of the food use inert ingredients for which wider certified limits have been proposed:

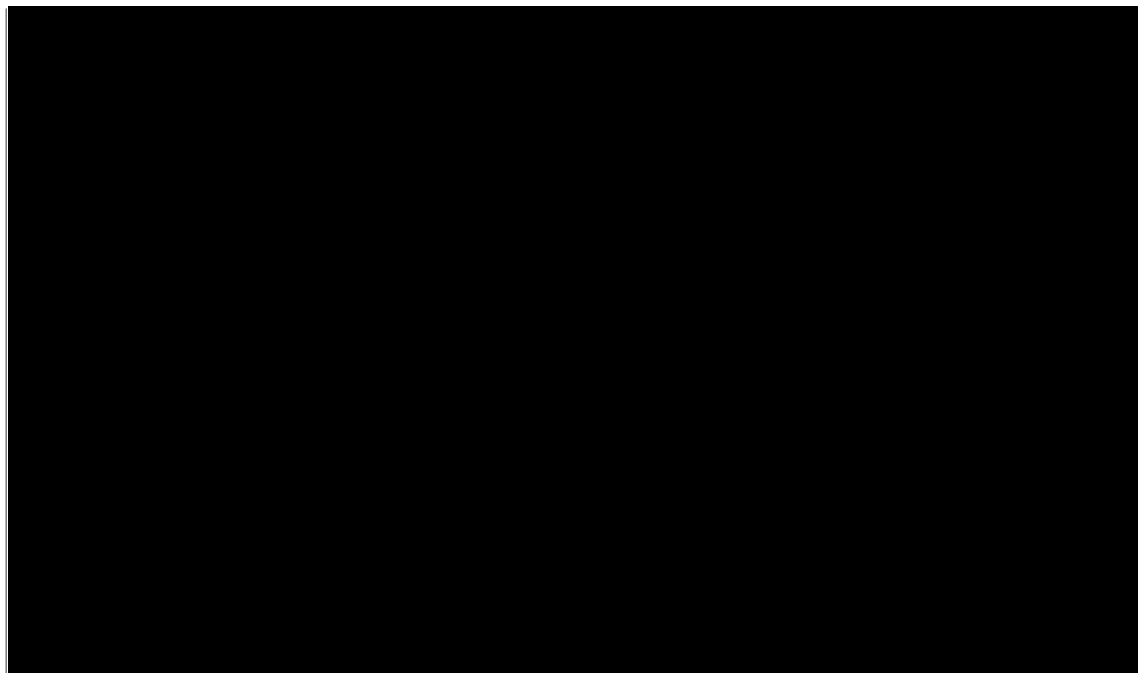
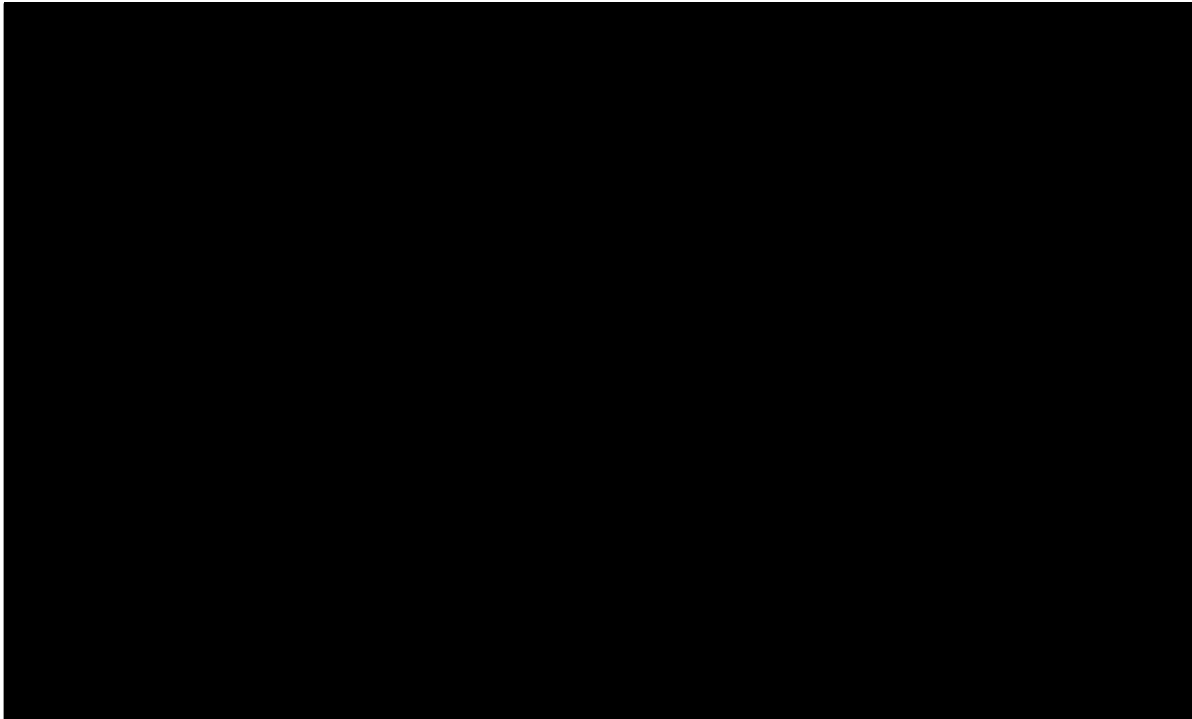


The registrant must provide proper justifications for proposing wider certified limits.

Inert ingredient information may be entitled to confidential treatment

CONFIDENTIAL APPENDIX

Proposed alternate CSF #3 (A030, dated 6-17-08)



*** Claimed confidential by submitter***